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Department of
Agriculture

Food Safety
And Inspection
Service

Technical
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Center

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AUDIT REPORT FOR NICARAGUA JUNE 4 THROUGH JUNE 11, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Nicaragua's meat inspection system from June 4 through June 11, 2002. All of the three establishments certified to export meat to the United States were audited. All of these were slaughter establishments that were also conducting deboning processing operations.

The last audit of the Nicaragua meat inspection system was conducted in June 2001. Three establishments (Ests. 04, 05, and 08) were audited and all were acceptable. Major concerns with Nicaragua's meat inspection system included:

1. Hand washing facilities in lavatories were not provided with hot running water as required in all three establishments. This deficiency was corrected.
2. Floors in the hallways of the freezers were in need of repairs in Establishment 5. The floors were repaired.
3. Knife at rectum station was not being sterilized properly after each carcass. Two knives were required to be used by the bungler, thus permitting adequate time for sterilization of the knives.
4. The portable evisceration table was not being cleaned and sterilized with hot water in Establishments 4 and 8. This deficiency was corrected.

Beef for manufacturing, carcasses and cuts, edible organs and head meat and tongues are eligible for export from Nicaragua.

From January to April 1, 2002, Nicaraguan establishments exported 10,496,124 pounds of fresh beef and beef products, beef edible organs, and beef processed products to the U. S. Port-of-entry (POE) rejections for transportation damage were 480 pounds (.045%). At the time of the audit, Nicaragua was exporting beef and beef products only.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Nicaragua's national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. All of the Nicaragua meat

establishments eligible to export to the U. S. were audited. The third was conducted by on-site visits to establishments. All of the establishments certified to export to the U.S. were audited. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella*. Nicaragua uses government laboratories for microbiological testing.

Nicaragua's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in each of the three establishments audited; one establishment (Est. 4) was recommended for a 30-day letter due to an inadequate *E. coli* testing program and improper sampling techniques. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

Entrance Meeting

On Tuesday, June 4, 2002, an entrance meeting was held in the offices of the Ministerio Agrpppecuario Y Forestal (MAG-FOR) in Managua, Nicaragua, and was attended by Leyla Umana, Director of National Laboratory of Biological Residues; Sonia Garcia, Director of National Laboratory of Veterinary Diagnostics; Omar Garcia, Director of Animal Health; Julio Hernandez, Minister DGPSA; Dr. Lisandro Herrera, Chief of Meat Inspection; Bertha Martinez, Chief of Registered Veterinary Medicine; Diego Velazquez, Chief of Department of Inspection and HACCP Certification; and Dr. Judd Giezentanner, International Audit Staff Officer, FSIS. Topics of discussion included the following:

1. Audit itinerary.
2. List of Certified Establishments.
3. Species Verification.

Headquarters Audit

Changes in the organizational structure of inspection since the last audit of the Nicaragua Meat Inspection system consist of the following: Dr. Diego Velazquez Pereira is now the Director of the Department of Inspection and HACCP Certification and Dr. Lisandro Herrera is the Chief of Meat Inspection.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called “the auditor”) observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the headquarters of the inspection service or at a district or regional office. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Label approval records such as generic labels, and animal raising claims.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.

No concerns arose as a result the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Nicaragua as eligible to export meat products to the United States were full-time Government of Nicaragua Meat Inspection employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Three establishments were certified to export meat products to the United States at the time this audit was conducted. Three establishments were visited for on-site audits. In all of the establishments visited, both Nicaraguan inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The MAG-FOR Nicaragua Residues Laboratory in Managua was audited on Friday, June 7, 2002. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable.

Nicaragua's microbiological testing for *Salmonella* and *E. coli* were being performed in a government laboratory, the Government Central Laboratory, and was acceptable.

Establishment Operations by Establishment Number

The following operations were being conducted in the three establishments:

Beef slaughter and boning - three establishments (4, 5, and 8)

SANITATION CONTROLS

Based on the on-site audits of establishments, Nicaragua's inspection system had controls in place for basic establishment facilities, condition of facilities equipment, product protection and handling and the establishment sanitation program

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A). The SSOPs were found to meet the basic FSIS regulatory requirements, with only occasional minor variations. Establishments 4 and 5 did not address preventive actions. The

Nicaraguan meat inspection officials and establishment officials assured this auditor that preventive actions would be properly addressed in the SSOP plans.

ANIMAL DISEASE CONTROLS

Nicaragua's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

RESIDUE CONTROLS

The National Residue Testing Plan for 2002 was being followed, and was on schedule. The Nicaraguan inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The Nicaraguan inspection system had controls in place to ensure adequate ante-and post-mortem inspection procedures and dispositions, control and disposition of dead, dying, diseased or disabled animals, humane handling and slaughter. The Nicaraguan Inspection Service was in the process of changing requirements for sanitizing of knives at areas where significant contamination of utensils was likely to occur, such as the bunging station and the evisceration station. They will require each operator to have two knives available so that each knife will remain in the sterilizer long enough for the heat treatment to be effective.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements, except that none of the three establishments adequately addressed preventive actions.

Testing for Generic *E. coli*

Nicaragua has adopted the FSIS regulatory requirements for *E. coli* testing.

Three of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements. However, *E. coli* testing was being performed in government laboratories instead of private laboratories.

Additionally, establishments had adequate controls in place to prevent meat products intended for Nicaraguan domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

The Nicaraguan inspection system controls [control of restricted product and inspection samples, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Three of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Nicaragua has adopted the FSIS regulatory requirements for *Salmonella* testing.

The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

Species Verification Testing

At the time of this audit, Nicaragua was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed by Nicaragua's national meat inspection official, Dr. Lisandro Herrera, who was a veterinarian with at least 30 years of experience in meat inspection.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were announced in advance and were conducted by individuals, at least once monthly, and sometimes two or three times within a month. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the central Department of Inspection and HACCP Certification offices in Managua, and were routinely maintained on file for a minimum of 3 years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, the Chief Meat Inspection Officer is empowered to conduct an in-depth review, and formulates a plan for corrective actions and preventive measures.

Enforcement Activities

Meat inspection officials carry out enforcement activities. The Chief of Meat and Poultry Inspection Services has the sole power to initiate all enforcement actions.

Exit Meetings

An exit meeting was conducted in Managua, Nicaragua, on Tuesday, June 11, 2002. The participants included Dr. Judd Giezantanner, International Audit Staff Officer, FSIS; Maria del Pilar Soler, translator; Dr. Leyla Umana, Director of the National Residue Laboratory; Mario Gonzalea Herrera, Chief of Servicios de Campo DISAAN; Omar Carcia Corrales Director of Animal Health; Sonia Maria, Director of the Laboratory of Animal Health; Denis

J. Salgada Fonseca, Director of DGPSA; Dr. Lisandro Herrera, Chief of Meat Inspection; and Dr. Diego Velazques Pereira, Chief of the Department of Inspection and HACCP Certification.

The following topics were discussed:

1. Requirements of a 30-day letter. This auditor was assured that Nicaraguan officials would ensure the fulfillment of the 30-day letter requirements.
2. A discussion was centered on the need for the development of a Food Security Management Team and procedures for food security from terrorist activities.
3. A discussion of Country of Origin Labeling.
4. *E. coli* testing program and sampling procedures. The officials assured this auditor that laboratory personnel had already conducted a training program for testing personnel for Establishment 4 personnel and also for sampling personnel of the other establishments.

CONCLUSION

The inspection system of Nicaragua was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Three establishments were audited. Establishment 4 was to be issued a 30-day letter by Nicaraguan meat inspection officials because of an inadequate *E. coli* testing plan and for poor execution of *E. coli* sampling procedures. The Nicaraguan meat inspection officials assured this auditor that all of the *E. coli* sampling personnel in the establishments would undergo training by laboratory personnel. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. Judd Giezentanner
International Audit Staff Officer

(Signed) Dr. Judd Giezentanner

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing
- D. Data collection instrument for Salmonella testing
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
5	√	√	√	√	√	√	√	√
4	√	√	√	√	√	√	√	√
8	√	√	√	√	√	√	√	√

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. review
5	√	√	√	√	√	√	√	√	√	√	√	√
4	√	√	√	√	√	√	√	√	√	√	√	√
8	√	√	√	√	√	√	√	√	√	√	√	√

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1. Written procedure	2. Sampler designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
5	√	√	√	√	√	√	√	√	√	√
4	√	no	no	√	√	√	√	√	√	√
8	√	√	No	√	√	√	√	√	√	√

The *E. coli* sampling program did not state the sampler (person responsible for sampling) in Est. 4, nor the sampling site for Est. 4 and Est. 8. The person observed doing the sampling did not use proper techniques. The Inspection Service had laboratory personnel conduct a training session for the samplers at all the establishments and on correct written sampling programs.

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
5	√	√	N/A	√	√	√
4	√	√	N/A	√	√	√
8	√	√	N/A	√	√	√